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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/469,733	12/21/99	ETTER J	42830-00060

025231
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EXAMINER	
MOEZIE,F	
ART UNIT	**PAPER NUMBER**
1653	6

DATE MAILED: 03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/469,733	Applicant(s) Etter
	Examiner F. T. Moezie	Group Art Unit 1653

☒ Responsive to communication(s) filed on *Dec 21, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-76* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-76* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

STATUS OF CLAIMS

Claims 1-76 are pending in this application.

RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a method for making an insulin containing particulate product, classified in class 514, subclass 4, for example.

II. Claims 20-68, drawn to a method for making multi-component particles containing insulin and a biocompatible polymer, classified in various class and subclasses depending on the structure of the elected active compounds.

III. Claims 69-76, drawn to a device, classified in class 604, subclass 232+.

1. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are distinct one from the other. Inventions are distinct because they have different objectives, different modes of operation, different functions, different effects and different protocols. Furthermore, the computer and the library searches are not co-extensive. A reference which would obviate claims drawn to one of the inventions, may not render obvious claims drawn to the other invention, absent ancillary evidence. Moreover, the consideration of patentability is different in each case. Hence, it would be an undue burden to examine both inventions in one application.

Inventions I or II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to dispense particulate of other drugs such as particulate of LHRH or growth hormone.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims of Group I and II inventions are generic to a plurality of disclosed patentably distinct species comprising:

A) species of anti-solvent fluid,

B) species of a first organic solvent,

C) species of second organic solvent, and

in the event applicant may elect Group II invention, an election of

D) species of a biocompatible polymer.

In any event applicant is to elect an Ultimate specie for species A), B), C) or D) and indicate claims reading thereon within the elected invention or draw claim(s) to the same.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention, an election of the species and an ultimate specie to be examined even though the requirement be traversed (37 CFR 1.143).

An ultimate specie of a compound is a compound wherein all of its variable parameters are accounted for.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F.T. Moezie whose telephone number is (703) 305-4508.

F.T. Moezie

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